

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 25

REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 10-14, 16 and 17 have been withdrawn from consideration by the Examiner. Claims 1-5, 7-9 and 15 have been rejected. Claims 1, 14 and 15 have been amended. Claims 10-13 and 16-17 have been canceled without prejudice. New claims 18 through 23 have been added. Support for these amendments is provided in the specification at pages 14-16, 32-33 and Example 1. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed October 2, 2003. Thus, the Examiner has withdrawn from consideration claims 6, 10-14, 16 and 17 and nucleic acid sequences other than SEQ ID NO:42 encoding SEQ ID 145. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 10-13, 16 and 17. Further, Applicants have amended the claims to be drawn to the elected sequence SEQ ID NO:42 encoding SEQ ID NO:145 and SEQ ID NO:41 the parent or related sequence to

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 26

SEQ ID NO:42. In light of the Examiner's acknowledgment that process claims that depend from or otherwise include all the limitations of the patentable product will be entered upon allowance of the product claim, Applicants have amended claim 14 to be drawn to claim 1 only and have indicated claim 6 to be withdrawn, not canceled. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Disclosure

The Examiner has objected to the specification because of the following informalities.

Specifically, the Examiner suggests that the trademarks "megaBACE" at page 35, line 10, "Green-5-UTP" at page 36, line 9, "FastTag" at page 37, line 12, "pDisplay" at page 51, line 17, "Retropack" and EcoPack2-293" at page 53, line 13, "ExpressSF", at page 58, line 25, "Calphos" at page 60, line 28 and "Effectene" at page 61, line 2, should be capitalized and accompanied by the generic terminology.

The Examiner also suggests that a blank appears at page 48, line 27 and page 75, line 15 in the phrase "yeast _mating system".

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 27

The disclosure has also been objected to for inclusion of embedded hyperlinks.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to capitalize the identified trademarks, correct the inadvertent typographical error in the phrase "yeast _-mating system" to state "--yeast α -mating system", a well known system in the art, and other inadvertent typographical errors in the specification noted during preparation of this response and to inactivate any hyperlinks or other forms of browser executable code. Generic terminology was already included by the identified trademarks in the specification and thus is not required.

No new matter has been added by these amendment. Withdrawal of this objection is respectfully requested in light of these amendments. No new matter has been added by these amendment. Withdrawal of this objection is respectfully requested in light of these amendments.

III. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph as the Examiner suggests

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 28

that the claimed invention lacks patentable utility. Specifically, the Examiner suggests that the Tables at pages 117-118 and 121-127 do not show a nexus between the presence or expression of SEQ ID NO:42 and lung cancer. Applicants respectfully traverse this rejection.

The instant application claims the benefit of priority from U.S. Provisional Application Serial No. 60/252,054, filed November 20, 2000, the entire contents of which were incorporated by reference in their entirety into the instant application. See page 1, lines 4-6 of the instant application. In the priority application, parent sequence SEQ ID NO:41, referred to therein as SEQ ID NO:33 (see Sequence Listing of instant application), was demonstrated by suppression subtractive hybridization to be a lung cancer specific marker. These experiments described at pages 26 through 29 of the provisional application, which demonstrate utility of the instant claimed invention, have been incorporated into the instant application as Example 1a at page 118, line 16. No new matter is added by this amendment.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement.

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 29

Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980).
Clearly identification of SEQ ID NO:33, a related sequence to SEQ ID NO:41 and 42 as being a lung cancer specific marker constitutes a pharmacological activity relevant to the asserted use as a diagnostic for lung cancer, thus satisfying the utility requirement.

Applicants have canceled claim 17 thus mooted rejections relating to this claim.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is respectfully requested in light of the claim amendments and the above remarks.

IV. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the recitation of "a nucleic acid molecule that selectively hybridizes to the nucleic acid molecules of (a) or (b)" and "a nucleic acid molecule having at least 60% identity to the nucleic acid molecule of (a) or (b)" encompasses a large genus of nucleic acid species not adequately described or disclosed.

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 30

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that structural features that could distinguish compounds in the genus from others are missing from the disclosure and that no common structural attributes identify the members of the genus. All claimed nucleic acid sequence are distinguished based upon their common structural similarities to reference sequences explicitly disclosed in the instant specification.

Further, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence hybridizes under stringent conditions and have defined these conditions in accordance with teachings at page 14 through 16 of the instant specification. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 90% identity with nucleic acid molecule of SEQ ID NO:41 or 42 or encoding SEQ ID NO:145 in accordance with teachings at page 32 through 33.

Detailed methodologies for ascertaining sequences which meet the structural limitations of the instant amended claims are set forth in the specification at page 13 through 16 and 32 through 33. Further methods for assessing percent sequence identity

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 31

and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:41 or 42 and their specificity in lung tumor tissues, Applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7-9, and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Examiner regards as the invention.

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 32

Specifically, the Examiner suggests that the claims are vague and indefinite for claiming more than was elected.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the elected SEQ ID NO:42 and its parent or related sequence, SEQ ID NO:41.

Further, the Examiner suggests that recitation of "selectively hybridizes" in claim 1 is vague, indefinite and incomplete because the term is a relative term one and no frame of reference is given.

Applicants respectfully disagree since what is meant by "selectively hybridizes" is described in detail in the specification at page 14. However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete this phrase and to clarify that the nucleic acid molecule hybridizes under defined stringent conditions in accordance with teachings at page 14-16.

In addition, the Examiner suggest that claim 15 is vague and indefinite because the "means" for determining the presence of the nucleic acid as required by the kit is not clearly defined in the specification or claims.

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 33

Applicants respectfully disagree.

Exemplary means contemplated for determining the presence of a nucleic acid sequence are described in the patent application at pages 95-96.

MPEP § 2173 is quite clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and

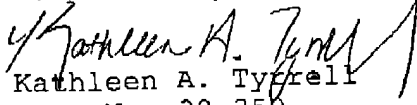
(C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. The content of the application in this case makes clear what is meant by stringent hybridization conditions and sets forth various means for detecting a nucleic acid in accordance with the claimed kits, thus meeting the requirements of 35 U.S.C. § 112, second paragraph. Further clarification in the claims is not required.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the above remarks and the amendments to the claims.

Attorney Docket No.: DEX-0273
Inventors: Macina et al.
Serial No.: 10/001,857
Filing Date: November 20, 2001
Page 34

VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted

Kathleen A. Tyrrell
Reg. No. 38,350

Date: June 8, 2004

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515